



Role for Research in Assessing the Impact of Medicare Part D Implementation on States and Low-Income Enrollees in Medicaid and Pharmacy Assistance Programs

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The implementation of Medicare Part D has highlighted numerous gaps in information and evidence-based research that will need to be filled in order to assess the impact of the Medicare drug benefit on the nearly 8 million low-income beneficiaries currently receiving drug coverage through Medicaid and state pharmacy assistance programs (SPAPs).¹

These concerns were brought to the forefront at an October 2004 conference entitled “An Invitational Summit for State Policymakers: Medicare Part D Implementation Issues,” co-sponsored by Rutgers Center for State Health Policy and State Coverage Initiatives of AcademyHealth, with funding from the Agency for Healthcare Research and Quality and additional support from The Robert Wood Johnson Foundation, The Commonwealth Fund, and the National Governors’ Association.

This brief summarizes some key concerns raised by states, advocates, and researchers during this conference and in the continuing dialogue taking place throughout our nation. We present some potential next steps in an effort to formulate a research agenda that is both informed by, and also helps to advance, the policy design and implementation. We also cite methodological and technical challenges that will need to be overcome in order to fully assess the implications of Part D on this vulnerable population.

Enrollment and Transitional Gaps in Coverage

Part D is a complex benefit that is considerably different from the coverage currently offered to

Medicaid and SPAP enrollees. As federal and state governments prepare to implement Medicare Part D under an ambitious, expedited timeframe, one immediate concern is to ensure a smooth transition for Medicare beneficiaries who currently receive prescription drug coverage through state programs.

Enrollment Concerns Include:

- Getting state benefit recipients enrolled in Part D plans and the low-income subsidies (LIS) initially and on an ongoing basis.
- Consideration of existing drug history and pharmacy networks in enrolling dually eligible Medicaid and Medicare recipients, and particularly long term care residents, who are vulnerable high-risk populations with special needs.
- Temporary gaps or loss of prescription drug coverage for duals during the transition process.
- Risk of inappropriate plan placement through random autoassignment process.
- Lack of understanding about the Special Enrollment Period, leading to individuals staying in inappropriate plans unnecessarily.
- Other enrollment issues that could lead to loss of coverage, such as choosing a plan with a premium above the LIS premium benchmark and not being able to pay the premium.
- Inability of SPAPs to autoenroll their enrollees into LIS or Part D plans, could lead either to loss of coverage or the state assuming costs for Medicare-covered benefits.²
- Lack of incentive for SPAP members to enroll in Part D or LIS.

With matched Medicaid and/or SPAP eligibility data and Part D and LIS enrollment data, researchers should evaluate the Part D enrollment process in these low-income populations and the degree to which gaps in coverage occurred.

Next Steps: Enrollment-related Research

- Determining enrollment behavior of different groups (i.e., institutionalized vs. non-institutionalized SPAP enrollees, community-based full duals vs. those in Medicare Savings Programs, and LIS eligibles vs. non-LIS eligibles).
- Assessing different SPAP outreach/education/enrollment/eligibility policies and determining their impact on enrollment rates to target future efforts.
- Determining impact of supplemental SPAP Medicare Part D wrap coverage on enrollment.
- Determining how many Medicaid/SPAP enrollees experienced a gap in coverage (and for how long the gap lasted), impact on drug utilization and health/quality of life, and costs to states because of adverse effects.
- For Medicaid beneficiaries who were autoassigned, assessing how well the random autoassignment process worked, their level of understanding about their new coverage, and whether they use Part D drug coverage.

Reduced Access to Necessary Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 transfers prescription drug coverage for low-income individuals from State governments to the private sector. This shift provides new opportunities for employing cost containment approaches currently used by the private sector but also creates the potential to negatively impact access to medically necessary medications.

Access-related Concerns Include:

- Use of closed formularies, other aggressive cost containment strategies, and increased copayments that have not been typically employed in Medicaid or SPAP programs.
- The impact of these strategies on access to necessary drugs, health status, and use of other health services has not been extensively studied.
- Lack of coverage for non-Part D drugs, which previously were covered by Medicaid or SPAPs, may lead to harmful complications if discontinued improperly.
- Impact of mid-year changes in formulary structure and ability to effectively inform dual eligibles of their option to switch plans.
- The interrelationship between Medicare Part D plans and state programs that elect to wrap around the Part D benefit and the impact on Part D plan formularies in those states.
- Part D appeals process may be a barrier to access and compliance.
- Disease Management programs in Medicaid, which seek to increase compliance with medication therapies in chronically ill persons, may be negatively affected by Part D plans.
- Ability to maintain adequate risk adjustment methodologies over time which discourage private insurers from market behaviors to avoid “bad-risk” that will reduce access for most vulnerable groups.

Since existing Medicaid and SPAP cost-containment policies vary by state, it is critical to conduct an analysis of Part D’s impact at the state-level in order to control for pre-existing trends, drug utilization behavior, and policies. This will require linking Part D enrollment, eligibility, and claims data with Medicare Parts A and B, and also Medicaid and SPAP claims data.

Next Steps: Access-related Research

- Measuring the impact of existing State cost-containment approaches that are similar to the private sector as a baseline assessment.
- Examining and tracking Part D formularies to determine how open or restrictive they are compared to existing State formularies.
- Determining the effect of Part D closed formularies in states that had open formularies or preferred drug lists.
- Determining the impact of not covering non-Part D drugs on drug utilization and outcomes for different subpopulations; along with the impact if a state provides wrap-around coverage.
- Assessing the separate effect of each cost-containment strategy on 1) compliance and use of essential vs. less essential medications; 2) drug expenditures; 3) health status and 4) use of other health care services.
- Measuring long term health outcomes related to Part D cost containment approaches.

- Increased enrollment in Medicaid and Medicare Savings Programs (MSPs) as a result of screening for other low-income programs during the LIS application process and following-up on leads data.
- Anticipated reduction in negotiating power for supplemental rebates from drug manufacturers.
- Increased utilization of other health care services (e.g., long term care) resulting from restricted access to necessary outpatient drugs.
- For SPAPs, it was expected that Part D would provide savings but estimates were considered premature as there was inadequate information on the enrollment process, plan formularies, and cost sharing structures.
- Although the federal government had estimated that SPAPs would save over \$600 million because of the LIS, this figure was based on a very ambitious 100% take-up rate and does not take into account the increased administrative costs of coordinating benefits with multiple plans.

Part D Financial Impact on Medicaid and SPAPs

CMS estimates that the total net savings to states from Part D will be \$7.9 billion for the five-year period of 2006-2010.³ State officials have expressed concern that the federal government has grossly overestimated the savings to Medicaid and SPAP programs.

Cost-related Concerns Include:

- Clawback payments to the federal government – due to the formula for calculating the clawback payment, many states estimate they would pay more in the first few years than if they had maintained control of the drug benefit and continued with their own cost containment strategies.
- Increased administrative costs for determining eligibility for LIS and follow-up on leads data from the Social Security Administration.

Next Steps: Research on Fiscal/Administrative Impact on States

- Measuring the increase in enrollment in Medicaid and MSPs as a result of LIS screening and outreach efforts, and the additional costs accrued by states to cover these new individuals.
- Tracking the administrative costs to Medicaid and SPAP programs for screening for Medicaid and MSPs, assisting enrollees to find a Part D plan, and coordinating with multiple plans.
- Assessing the residual impact of the Medicare Part D best price exemption on Medicaid drug prices for the non-Medicare eligible population.
- Calculating the net savings that Medicaid and SPAPs realize as a result of Part D, taking into account the clawback and other costs.
- Comparing the net savings to Medicaid and SPAPs by region, stringency of formulary structure, other cost containment strategies, and availability of state wrap-around benefits.

Methodological and Policy Challenges

One of the biggest challenges to studying the impact of Part D on Medicaid and SPAP enrollees is collecting or accessing meaningful reliable data specific to these populations. Ideally, the best data source for use in researching enrollment and access as described above is Part D linked longitudinal enrollment and claims data that can also be linked to historical and current Medicaid and SPAP enrollment and claims data. The degree to which these data will be publicly available is still in question and of great concern to both the research community and state officials interested in monitoring the impact of Part D and various drug utilization control strategies on the use of other health services in Medicaid and Medicare. Based on current interpretations of the statute, it is possible that Part D enrollment and claims data will not be publicly available or will only be available in de-identified form and not linkable to other data sets.

In the absence of these data in the immediate future, states and researchers may wish to partner in developing targeted pre/post surveys or focus groups of enrolling and non-enrolling Medicaid and SPAP enrollees and/or their caregivers who assisted in enrollment decisions.

The ideal research design for assessing the impact of Medicare on enrollees of Medicaid

and state pharmacy assistance programs pre- and post-MMA implementation is a time-series with comparison groups. Since such carefully controlled longitudinal studies take a considerable amount of time to complete, they are often substituted with simple pre- and post-utilization studies that may attribute cause-and-effect relationships to trends that existed prior to the intervention. The study design is further complicated by the fact that multiple interventions will be implemented simultaneously, making it difficult to single out the effects of any one drug utilization control strategy.

Given these methodological hurdles, the best strategy may be a multi-pronged approach which includes both longer term quantitative analysis of administrative data coupled with shorter term qualitative policy analysis that includes tracking states' experiences with Part D implementation.

Endnotes

1. This includes 6.4 million individuals dually eligible for Medicaid and Medicare and 1.5 million individuals enrolled in state pharmacy assistance programs for low-income persons ineligible for Medicaid.
2. SPAPs have been granted the authority to perform Intelligent Random Assignment but will still have to coordinate with multiple Part D plans.
3. Centers for Medicare and Medicaid Services. Federal Register. January 28, 2005. Vol. 70, No. 18. P. 4455.



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